

**Congress of the United States**  
**Washington, DC 20515**

February 12, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Verma:

We write to commend the administration and your leadership at the Centers for Medicare and Medicaid Services (CMS) for ensuring Medicare patients nationwide have access to innovative and life-saving treatments including chimeric antigen receptor T-cell (CAR T-cell) therapy approved by the Food and Drug Administration (FDA). The finalized National Coverage Determination (NCD) was a monumental first step in providing access to these revolutionary medicines to Medicare patients.<sup>1</sup> Building on policies that complement our shared goals, we must ensure that hospitals are appropriately reimbursed so they may continue to provide CAR T-cell therapy to America's seniors. To this end, we request CMS to consider establishing a Medicare Severity-Diagnosis Related Group (MS-DRG) specific for CAR T-cell therapy in the Fiscal Year (FY) 2021 Inpatient Prospective Payment System.

As you know, immunotherapy is a rapidly advancing field that is delivering promise for many patients diagnosed with life-threatening cancers, many of whom have exhausted all available treatment options. The NCD provides for consistent access, while ongoing programs at the FDA and the National Cancer Institute will lead to better understanding of which patients will benefit from these therapies. The interagency partnerships that led to the expansion of the Center for International Blood and Marrow Transplant Research Cellular Therapy Registry allows for a long-term follow up and scientific study of patients, and it complements the FDA's robust postmarketing surveillance and risk assessment programs and will yield additional insights about the value of these advancements for Medicare patients.

We also appreciate CMS' decision to grant CAR T-cell therapy a new technology add-on payment (NTAP) and to increase the maximum add-on payment amount, but this is only a temporary solution as the CAR T-cell therapy NTAP is anticipated to expire on September 30, 2020.<sup>2</sup> Reimbursement remains a barrier to inpatient hospitals treating Medicare patients with CAR T-cell therapy, and these hospitals face a reimbursement cliff if CMS does not act to create a permanent payment mechanism by FY 2021. This reimbursement gap potentially leaves providers with large deficits, including the additional costs of care associated with furnishing CAR T-cell therapy, and will likely halt patient access.

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<sup>1</sup> Centers for Medicare and Medicaid Services, Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N), available at: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291>.

<sup>2</sup> Centers for Medicare and Medicaid Services, Fiscal Year (FY) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System (CMS-1716-F), 84 FR 42044.


Rural patients already face potential access challenges due to their lack of immediate proximity to authorized treatment centers and highlight the importance of maintaining access to those facilities located within reasonable proximity that can provide this therapy to neighboring rural areas. However, the stress of the reimbursement gap can have a detrimental effect on facilities that treat a large share of the Medicare patient volume. We are concerned that there will be a negative impact on the access landscape, especially for Medicare patients living in rural areas.

Establishing an MS-DRG for FY 2021 will be an important step to improve access for Medicare patients in need of cancer treatment regardless of where they live. Thank you again for continuing to work with us and we hope to follow up with you on the details of this proposal to ensure America's seniors have the best possible access to our health care system's most exciting advances.

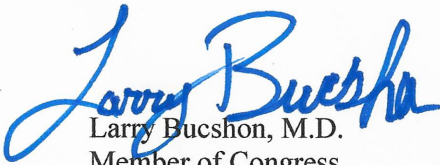
Sincerely,



Roger Marshall, M.D.  
Member of Congress



Suzan DelBene  
Member of Congress



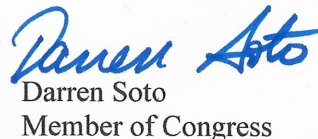
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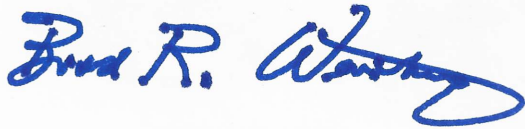


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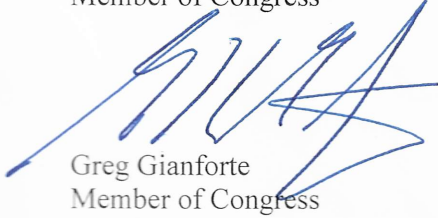


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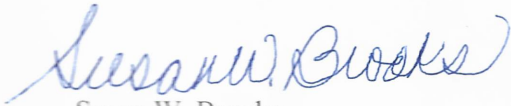




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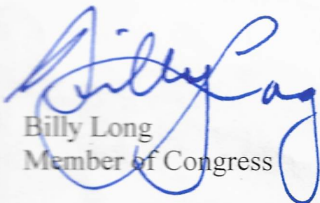
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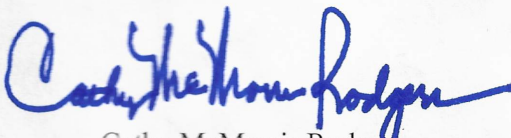
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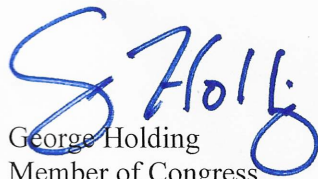
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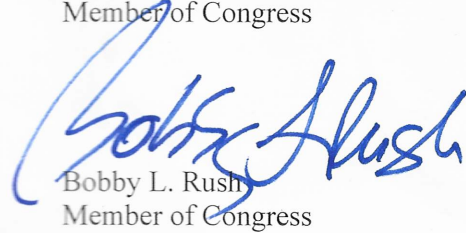
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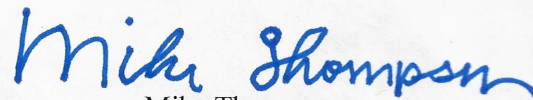
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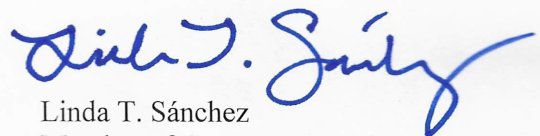
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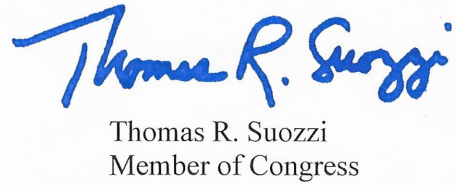
Mike Thompson  
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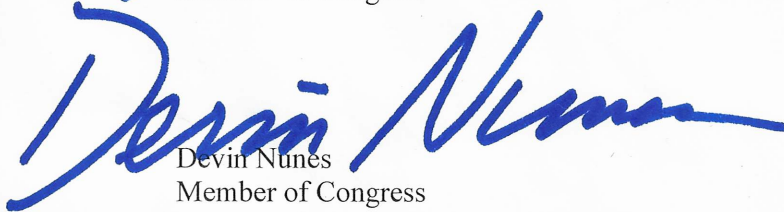
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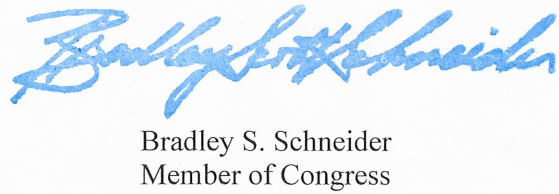
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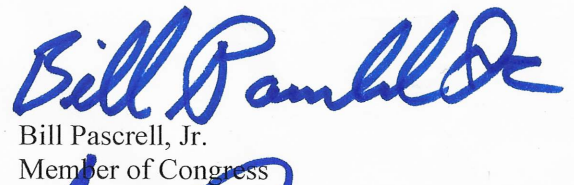
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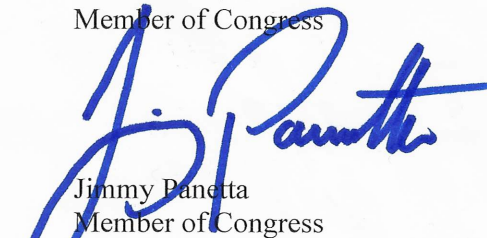
Richard Hudson  
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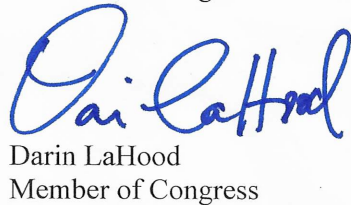
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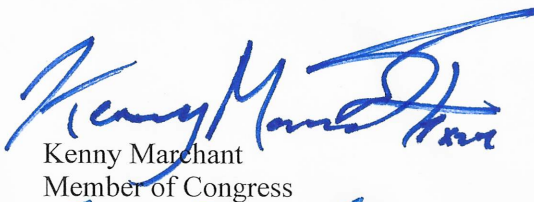
Jimmy Panetta  
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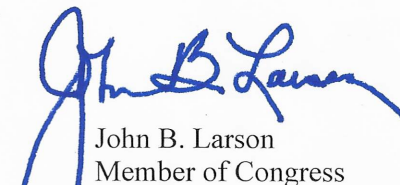
Darin LaHood  
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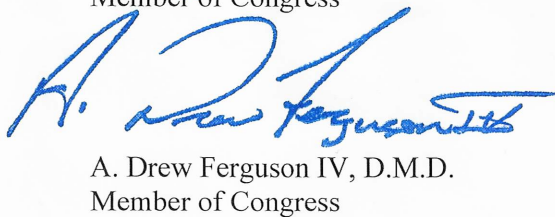
Adrian Smith  
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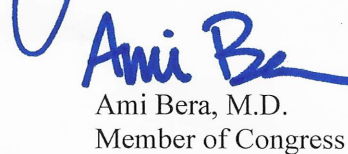
Kenny Marchant  
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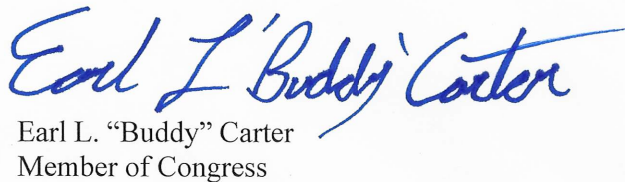
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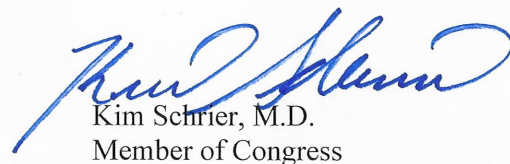
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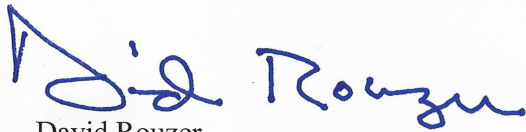
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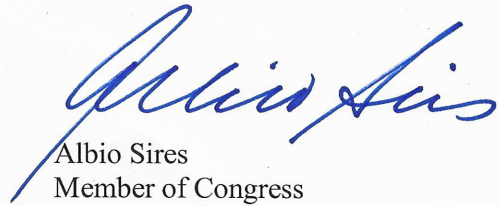
Lizzie Fletcher

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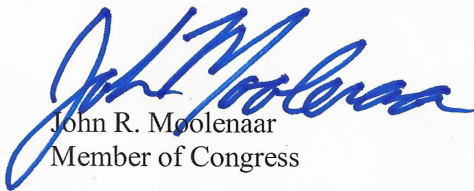




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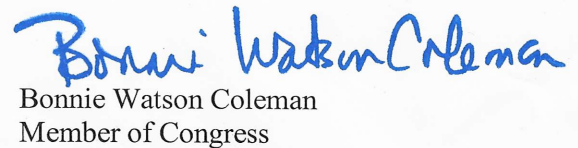
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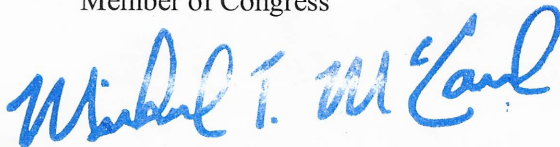
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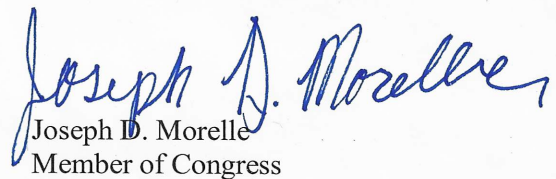
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